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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,465	12/05/2000	Barbara P. Wallner	10274-006002	7066

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/07/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	09/730465	Applicant(s) WALLNER
	Examiner GAMBEL	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/16/02

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 1-54 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requireme

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 11/5/00 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disappr d by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

PAPER NO. 13

DETAILED ACTION

1. Applicant's election of the species LFA-3 in Paper No. 7, filed 4/16/02, is acknowledged.

Upon reconsideration given the prosecution of parent application USSN 04/466,465, filed 6/6/95, now U.S. Patent No. 6,162,432, all claims and species are under consideration in the instant application to advance compact prosecution.

Claims 1-54 are under consideration in the instant application.

2. The filing date of the instant claims appears to the filing date of priority application USSN 07/862,022, filed 4/2/92.

Priority application USSN 07/770,969, filed 10/7/91 does not support the broader claims of the instant application.

If applicant desires priority prior to 10/7/91; applicant is invited to point out and provide documentary support for the priority of the instant claims.

In addition, applicant should indicate for the record that all of the claimed limitations have written support and priority back to USSN 07/862,022, filed 4/2/92.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending applications, specific reference to the earlier filed applications must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents.

5. Formal drawings, filed 12/5/00, comply with 37 CFR 1.84.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

7. Applicant is required to provide the full citation (e.g., volume number, page numbers, year of publication) for the references indicated on the Information Disclosure Statement, filed 6/14/02 (Paper No. 9). Applicant may provide such information in the next communication and the examiner will transcribe this information on the Information Disclosure Statement directly.

8.The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the TS2/9 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Given the disclosure and the claims encompassing the instant 1E6, HC-1B11, 7A6 and 8B8 antibodies produced by the hybridomas designated ATCC HB 10693, 10694, 10695 and 10696, respectively set forth in parent application USSN 08/466,465, now U.S. Patent No. 6.162.432 (1449; #AE); the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to 1E6, HC-1B11, 7A6 and 8B8 antibodies have been satisfied.

10. Claim 12 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite in the recitation of "TS2/9" because its characteristics are not known. The use of "TS2/9" antibody as the sole means of identifying the claimed antibody and hybridoma renders the claim indefinite because "TS2/9" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation to define completely distinct hybridomas / cell lines / biological materials.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

11. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,162,432 (1449; #AE) in view of well known use of combination therapy with PUVA, chemotherapy and UV light in the treatment of skin conditions such as psoriasis known and practice at the time the invention was made, as evidenced by Merck Manual of Diagnosis and Therapy, Sixteenth Edition (edited by Berkow et al., Merck & Co., Inc. Rahway, NJ, 1992, particularly 2435-2444), Boger et al. et al. (U.S. Patent No. 5,122,514) and Rovee et al. (U.S. Patent No. 4,579,844).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to the same or nearly the same methods of treating skin conditions with the same or nearly the same inhibitors of the CD2/LFA-3 interaction. The instant claims primarily differ from the patented claims by comprising the use of inhibitors of the CD2/LFA-3 interaction with known methods of treating skin conditions such as PUVA, chemotherapy and UV light. Methods of treating skin conditions such as PUVA, chemotherapy and UV light were well known and practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 2-3, overlapping paragraph of the instant specification and as evidenced by the Merck Manual of Diagnosis and Therapy, Sixteenth Edition (edited by Berkow et al., Meck & Co., Inc. Rahway, NJ, 1992, particularly 2435-2444). Boger et al. Teach the known application of combination therapy with PUVA, UV light and chemotherapy in the treatment of psoriasis at the time the invention was made (see column 58, paragraph 3). Similarly, Rovee et al. teach combination therapy was known and practiced at the time the invention was made for inflammatory skin disorders and conditions wherein the combination provides more rapid and dramatic improvement than either drug alone, the combination is equally effective at lower concentrations than either drug alone, which can result from the drugs or treatment from acting on different aspects of the inflammatory response (see column 2, paragraph 2). One of ordinary skill in the art at the time the invention was made would have been motivated to combine the use of inhibitors of the CD2/LFA-3 interaction as set forth the patented claims of U.S. Patent No. 6,162,432 in combination with the known and practiced methods of PUVA, chemotherapy and UV light in the treatment of skin conditions such as psoriasis. It was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. For the reasons and prosection set forth in parent application USSN 08/466,465, now U.S. Patent No. 6,162,432, the instant claims appear to be free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
April 4, 2003